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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,732	07/25/2001	Joseph Atabekov	0933-0169P	5590

2292 7590 07/01/2003

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/01/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/911,732	ATABEKOV ET AL.
	Examiner	Art Unit
	Konstantina Katcheves	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 19-39 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 21 and 22 is/are allowed.

6) Claim(s) 19,20,25,27,31 and 34-37 is/are rejected.

7) Claim(s) 23,24,26,28-30,32 and 33 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. 09/424793.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 19-39 are pending in the present application. This Office action is in response to Paper No. 11, filed 10 April 2003.

### ***Response to Amendment***

The rejection of claims 26, 36 and 37 under 35 U.S.C. 112, first paragraph has been withdrawn in view of Applicant's arguments filed 10 April 2003.

The rejection of claims 23 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of Applicant's arguments filed 10 April 2003.

Claims 19, 20, 25, 27, 31, 34-36 and 37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al. (Journal of Virology Vol.65 no.6 1991) for the reasons of record and those set forth below.

### ***Response to Arguments***

Claims 19, 20, 25, 27, 31, 34-36 and 37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al. (Journal of Virology Vol.65 no.6 1991) for the reasons of record and those set forth below.

As discussed in the prior Office action, Thomas et al. teach a bicistronic vector comprising a full-length clone of cowpea mosaic virus middle component RNA (CPMV M-RNA) with a T7 RNA promoter. The CPMV M-RNA has two functional initiation sites one at the 5' end and the other at an internal initiation site, such as an IRES of the instant claims. Applicant has argued that the CPMV mRNA of Thomas et al. does not contain an IRES and is

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rather "an artifact of a poorly controlled experiment." Applicant states that the IRES activity is from the ODC gene itself. See Applicant's Amendment page 5. The fact that the IRES activity of Thomas et al. is an artifact of the ODC gene in which the CPMV middle component was inserted does not obviate Thomas et al. as prior art.

Applicant is reminded that claims are given their broadest reasonable interpretation in view of the supporting disclosure and limitations are not read into the claims. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). The claims merely require an IRES as a component of the recombinant nucleic acid sequence. The fact that the IRES is from the ODC gene of Thomas et al. does not overcome the present rejection. The recombinant nucleic acid of Thomas et al. does comprise an IRES component as claimed and thus meets the limitations of the present invention.

Applicant has also pointed to references and examples regarding the methods to identify sequences an IRES require tests on the expression of a 5' distal reporter gene. The fact that Thomas et al. does not use such a method to confirm the presence of an IRES does not overcome the present rejection because, as discussed above, Thomas et al. does disclose the product claims.

#### ***Allowable Subject Matter***

Claims 21 and 22 are allowable.

Claims 23, 24, 26, 28-30, 32 and 33 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

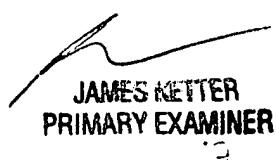
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
June 30, 2003



JAMES KETTER  
PRIMARY EXAMINER